

REMARKS

Claims 1-20 are currently pending in the application, claims 1, 4, 9, 12 and 17-20 have been amended, and claims 21-24 have been added. Support for the claim amendments may be found throughout the specification and claims as originally filed. In particular, support for new claims 21-24 may be found on pages 9-13 of the instant specification. No new matter has been added.

The amendments to the claims should in no way be construed as an acquiescence to any of the Examiner's rejections. The amendments are being made to more clearly define the invention. Applicants reserve the option to further prosecute the same or similar claims in the instant or in a subsequent patent application.

Rejection of Claims Under 35 U.S.C. § 103

Claims 1-8, 18 and 19 stand rejected under 35 U.S.C. § 103 (a) as being unpatentable over Japanese Patent Application No. 10-112393, Kokai Patent No. 11-5750 and Jonasse et al. (U.S. 6,274,626).

The Examiner states that "[t]he Japanese abstract teaches the use of Ketotifen in combination with antihistamine agents such as chlorpheniramine for the treatment of ocular conditions such as conjunctivitis" and that Jonasse et al. teaches "the use of pheniramine as an antihistamine being used for treating ocular allergies." The Examiner further contends that "[i]t would have been obvious to a person skilled in the art to add pheniramine to the Japanese reference, considering that Jonasse et al. teach [sic] the use of pheniramine for the treatment of ocular allergies."

Although the Japanese Patent teaches ketotifen in combination with chlorpheniramine, the patent requires that these antihistamines, each alone or in combination be formulated with a vasoconstrictor e.g., tetrahydrozoline, naphazoline, oxymethazoline, or phenylephrine (See for e.g., working examples 1-5 and Tables 1 and 2 of the Japanese Patent).

Therefore, contrary to the Examiner's position, the combined teachings of the Japanese Patent and Jonasses et al., does not teach a formulation of ketotifen and pheniramine for treatment of ocular allergies, but at best teaches the use of pheniramine alone or in conjunction

with ketotifen in combination with a vasoconstrictor for treatment of ocular conditions such as conjunctivitis.

In contrast, claims 1-8, 18 and 19 as amended are directed to pharmaceutical compositions and uses thereof, wherein the pharmaceutical compositions consist of ketotifen and pheniramine as the only active ingredients (i.e. the pharmaceutical compositions do not include a vasoconstrictor). Applicants findings (shown for example, in Table 1 and Figures 1, 2, 4, and 6) that the combination of ketotifen with pheniramine better relieves itching and redness associated with ocular allergies than either ketotifen or pheniramine alone is a surprising finding that is not taught or suggested by the Japanese patent alone or in combination with the teachings of Jonasses et al.. Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection.

Claims 9-16 stand rejected under 35 U.S.C. § 103 (a) as being unpatentable over Crespo et al. (U.S. Patent application no. 20020037297). The Examiner states that Crespo et al. teaches the use of antazoline or azelastine as an antihistamine for the treatment of ocular allergy such as conjunctivitis. However, the Examiner acknowledges that Crespo et al. does not teach that use of antazoline and azelastine alone is enough for treating rhinitis, conjunctivitis, cold, cold-like and/or flu symptoms and that an effective formulation must additionally contain a topical decongestant (i.e., an alpha-adrenergic agonist).

As currently amended claims 9-16 are directed to pharmaceutical compositions and uses thereof, wherein the pharmaceutical compositions consist of azelastine and antazoline as the only active ingredients (i.e. the pharmaceutical compositions do not include a decongestant), Applicants respectfully request reconsideration and withdrawal of this rejection.

Finally, claims 17 and 20 stand rejected under 35 U.S.C. § 103 (a) as being unpatentable over Crespo et al. (U.S. Patent application no. 20020037297), further stating that Crespo et al. “also teaches the use of a short acting antihistamine such as levocabastine and long acting antihistamines such as loratidine.”

Claims 17 and 20 as amended are directed to pharmaceutical compositions “consisting of:” (i) an effective concentration of azalastine and an effective concentration of a short-acting antihistamine agent and (ii) an effective concentration of antazoline and an effective concentration of a long-acting antihistamine agent, respectively. Because the teachings of

Crespo et al., require the presence of a decongestant and claims 17 and 20 do not provide for the presence of a decongestant, Applicants respectfully request reconsideration and withdrawal of this rejection.

CONCLUSION

Applicants consider the Response herein to be fully responsive to the referenced Office Action. Based on the above, it is respectfully submitted that this application is in condition for allowance. Accordingly, allowance is requested. If a telephone conversation with Applicant's Attorney would expedite prosecution of the above-identified application, the Examiner is urged to call the undersigned at (617) 832-1294.

Applicants believe that extra claim fees are due in conjunction with entering of this response. The Commissioner is hereby authorized to charge any deficiencies (or credit any overpayment) to Deposit Account Number **06-1448, Reference ORA-001.01.**

Respectfully submitted,

By:  _____

Beth E. Arnold
Reg. No. 35,430
Attorney for Applicants

Patent Group
FOLEY HOAG LLP
155 Seaport Blvd.
Boston, MA 02210-2600
Telephone: (617) 832-1294
Facsimile: (617) 832-7000

Dated: January 4, 2005

Customer No. 25181